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10/528,926

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Lone Andersen

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24126

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EXAMINER

DEES, NIKKI H

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,926	<b>Applicant(s)</b> ANDERSEN ET AL.	
	<b>Examiner</b> Nikki H. Dees	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,10-13 and 15-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,10-13 and 15-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 5, 2009, has been entered.
2. Claims 1, 2, 4-6, 8, 10-13 and 15-66 are currently pending in the Application. Claim 3 has been cancelled.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 6 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 6 claims a polymer with a molecular weight in the range of 500-19,000 g/mol. It is unclear if this is the weight average molecular weight (Mw) or the number

average molecular weight (Mn). For purposes of examination, the weight range will be interpreted as the number average molecular weight.

6. Claim 26 claims a chewing gum “substantially free” of non-biodegradable polymers. It is unclear how much, or how little, non-biodegradable polymer may be present in the chewing gum for the gum to be considered “substantially free” of said polymers.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 4-6, 8, 10-13, 15-17, 20-43, 46, 51-53, and 63-66 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Bunczek et al. (6,013,287).

9. Regarding claims 1, 2, 5, 8, 12, 16, 22, 23-27 and 63-66, Bunczek et al. disclose a chewing gum comprising at least one polyester polymer, wherein at least one of said polyester polymers is produced through the reaction of an alcohol or derivative thereof and an acid or derivative thereof. The teaching “at least one” is considered to meet Applicant’s claims to two biodegradable polymers as “at least one” clearly indicates that there could be more than one of the polymers present. The chewing gum also comprises a polyester polymer functioning as an elastomer plasticizer (col. 9 lines 41-

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44). Stated advantages of the invention are a gum base that is biodegradable, and that traditional elastomers and elastomer plasticizers are replaced with other polymers, indicating that the chewing gum of the invention may be substantially or totally free of non-biodegradable polymers (col. 2 lines 61-64).

10. Regarding claim 2, the polymers may be hydrophilic, depending on the amount of fatty acids/alcohols utilized in the invention (col. 3 lines 10-64). A less hydrophobic polyester is understood to be more hydrophilic.

11. Regarding claims 22-27, the polyester of Bunczek et al. may be used as elastomers and/or elastomer plasticizers in a gum base, comprising up to 80% by weight of the gum base. Other chewing gum ingredients include softeners and fillers (col. 9 lines 54-55).

12. Regarding claims 28-34, Bunczek et al. teach the chewing gum comprising flavoring agents in an amount ranging from about 0.1 to 15% by weight, preferably about 0.2 to 5% by weight. A number of conventional chewing gum flavoring agents are taught (col. 11 lines 57-67).

13. Regarding claims 35-40, sweeteners are taught for use in the chewing gum in an amount ranging from about 5% to 95% by weight of the gum. High-intensity sweeteners may be used in an amount ranging from about 0.02 to 8% by weight. High intensity sweeteners taught include sucralose, aspartame and alitame (col. 11 lines 11-14; 26-31; 39-45).

14. Regarding claims 41-43, the chewing gum may comprise softener in an amount ranging from about 0.5 to 15% by weight. Softeners include lecithin (col. 11 lines 3-5).

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15. Regarding claims 51 and 52, the chewing gum base may comprise filler in an amount ranging from 4 to 35 weight % (col. 9 line 67). This would result in the filler in the range as claimed in the chewing gum.

16. Regarding claim 53, the chewing gum may comprise desired color (col. 10 line 67).

17. Bunczek et al. are silent as to the  $M_n$  of their different biodegradable polymers functioning as elastomers and elastomer plasticizers in their invention. They are also silent as to the  $T_g$  of the different polymers.

18. However, given that the polyester polymers as taught by Bunczek et al. are to be used in chewing gums in place of conventional elastomers, elastomer plasticizers, and resins, the same functions as claimed by Applicants, it would have been considered obvious to utilize polymers having molecular weights ( $M_n$ ) and  $T_g$ s in the ranges as claimed, absent any convincing arguments or evidence to the contrary. The  $M_n$  and  $T_g$  of the polymers used in chewing gums are known to affect the textural/chewing properties of the gum. One of ordinary skill would have been able to optimize the  $M_n$  and  $T_g$  of the polymers utilized in the chewing gum through no more than routine experimentation in order to achieve the desired chewing properties.

19. Claims 18, 19, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (6,013,287) in view of Grijpma et al. (5,672,367).

20. Bunczek et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

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21. Bunczek et al. are silent as to their chewing gum comprising polyester polymers wherein the polymer is obtained by the polymerization of cyclic esters.

22. Regarding claims 18, 19, and 47-50, Grijpma et al. teach biodegradable polyester polymers for use in chewing gums produced from lactones in combination with cyclic esters as claimed by Applicants. Specific monomers taught to be polymerized include  $\epsilon$ -caprolactone and trimethylene carbonate (col. 1 lines 50-55).

23. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum substantially free from non-biodegradable polymers would have found it obvious to combine the polymers of Bunczek et al. with the polymers of Grijpma et al. in order to provide a chewing gum having desirable chewing properties while at the same time being substantially biodegradable. As all of the polymers of the instant claims are known in the prior art for inclusion in chewing gums, one of ordinary skill would have been able to combine them into one chewing gum base in order to employ different properties of the polymers to provide a chewing gum product having the most favorable chewing and degradation properties. In the absence of unexpected results, this combination of known polymers is considered to be no different than the combination of non-biodegradable polymers for inclusion in chewing gums.

24. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (6,013,287) in view of Li et al. (6,153,231).

25. Bunczek et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

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26. Bunczek et al. are silent as to their chewing gum comprising active agents.

27. Li et al. teach pharmaceutical agents to be added to chewing gums comprising biodegradable polymers (col. 7, lines 60-61).

28. One of ordinary skill in the art at the time the invention was made wishing to incorporate active (pharmaceutical) agents into the chewing gum of Bunczek et al. would have found it obvious to include pharmaceutical agents as taught by Li et al. as it was known in the art to include active ingredients in chewing gum preparations. Undue experimentation would not have been required, and there would have been a reasonable expectation that the chewing gum of Bunczek et al. would have been a suitable delivery medium for the desired active ingredients.

29. Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (6,013,287) in view of Meyers (5,433,960)

30. Bunczek et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

31. Bunczek et al. are silent as to their chewing gum being coated.

32. Meyers teaches coated chewing gum, wherein the coating comprises polyols, film forming agents, and additives as claimed (col. 3 lines 46-53). The coating may also comprise sugar-free coating agents (col. 10 lines 49-54).

33. One of ordinary skill in the art at the time the invention was made would have found it obvious to coat the chewing gum of Bunczek et al. with a coating as taught by Meyers in order to provide storage stability to the chewing gum since it is well known to

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coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective. Additionally, coating the chewing gum of Bunczek et al. would not have required undue experimentation as one of ordinary skill would have been familiar with the coating of chewing gum products as claimed.

34. Claims 1, 2, 4-6, 8, 10-13, 15-17, 20-43, 46, 51-53, and 63-66 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Cook et al. (6,441,126).

35. Regarding claims 1, 2, 5, 8, 12, 16, 22, 23-27 and 63-66, Cook et al. disclose a chewing gum comprising at least one polyester polymer. The teaching "at least one" is considered to meet Applicant's claims to two biodegradable polymers as "at least one" clearly indicates that there could be more than one of the polymers present. The polyester polymers may function as elastomers and/or elastomer plasticizer (Abstract; col. 7 lines 56-60). The polyester of Cook et al. may be used as elastomers and/or elastomer plasticizers in a gum base, comprising up to 80% by weight of the gum base. Other chewing gum ingredients include softeners and fillers (col. 7 lines 60-65).

36. Regarding claims 28-34, Cook et al. teach the chewing gum comprising flavoring agents in an amount ranging from about 0.1 to 15% by weight. Any known flavoring agent may be utilized in the composition to provide the desired flavor (col. 10 lines 13-25).

37. Regarding claims 35-40, sweeteners are taught for use in the chewing gum in an amount ranging from about 5% to 95% by weight of the gum. High-intensity sweeteners

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may be used in an amount ranging from about 0.02 to 8% by weight. High intensity sweeteners taught include acesulfame and alitame (col. 9 lines 31-35; 47-65).

38. Regarding claims 41-43, the chewing gum may comprise softeners, including lecithin, in an amount ranging from about 0.5 to 15% by weight (col. 9 lines 23-25).

39. Regarding claims 51 and 52, the chewing gum base may comprise filler in an amount ranging from 4 to 35 weight % (col. 8 line 20). This would result in the filler in the range as claimed in the chewing gum.

40. Regarding claim 53, the chewing gum may comprise the desired color (col. 9 lines 16-22).

41. Cook et al. are silent as to the Mn of their different biodegradable polymers functioning as elastomers and elastomer plasticizers in their invention. They are also silent as to the  $T_g$  of the different polymers.

42. However, given that the polyester polymers as taught by Cook et al. are to be used in chewing gums in place of conventional elastomers and elastomer plasticizers, the same function as claimed by Applicants, it would have been considered obvious to utilize polymers having molecular weights (Mn) and  $T_g$  s in the ranges as claimed, absent any convincing arguments or evidence to the contrary. The Mn and  $T_g$  of the polymers used in chewing gums are known to affect the textural/chewing properties of the gum. One of ordinary skill would have been able to optimize the Mn and  $T_g$  of the polymers utilized in the chewing gum through no more than routine experimentation in order to achieve the desired chewing properties.

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43. Claims 18, 19, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (6,441,126) in view of Grijpma et al. (5,672,367).

44. Cook et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

45. Cook et al. are silent as to their chewing gum comprising polyester polymers wherein the polymer is obtained by the polymerization of cyclic esters.

46. Regarding claims 18, 19, and 47-50, Grijpma et al. teach biodegradable polyester polymers for use in chewing gums produced from lactones in combination with cyclic esters as claimed by Applicants. Specific monomers taught to be polymerized include  $\epsilon$ -caprolactone and trimethylene carbonate (col. 1 lines 50-55).

47. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum substantially free from non-biodegradable polymers would have found it obvious to combine the polymers of Cook et al. with the polymers of Grijpma et al. in order to provide a chewing gum having desirable chewing properties while at the same time being substantially biodegradable. As all of the polymers of the instant claims are known in the prior art for inclusion in chewing gums, one of ordinary skill would have been able to combine them into one chewing gum base in order to employ different properties of the polymers to provide a chewing gum product having the most favorable chewing and degradation properties. In the absence of unexpected results, this combination of known polymers is considered to be no different than the combination of non-biodegradable polymers for inclusion in chewing gums.

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48. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (6,441,126) in view of Li et al. (6,153,231).

49. Cook et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

50. Cook et al. are silent as to their chewing gum comprising active agents.

51. Li et al. teach pharmaceutical agents to be added to chewing gums comprising biodegradable polymers (col. 7, lines 60-61).

52. One of ordinary skill in the art at the time the invention was made wishing to incorporate active (pharmaceutical) agents into the chewing gum of Cook et al. would have found it obvious to include pharmaceutical agents as taught by Li et al. as it was known in the art to include active ingredients in chewing gum preparations. Undue experimentation would not have been required, and there would have been a reasonable expectation that the chewing gum of Cook et al. would have been a suitable delivery medium for the desired active ingredients.

53. Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (6,441,126) in view of Meyers (5,433,960)

54. Cook et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

55. Cook et al. are silent as to their chewing gum being coated.

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56. Meyers teaches coated chewing gum, wherein the coating comprises polyols, film forming agents, and additives as claimed (col. 3 lines 46-53). The coating may also comprise sugar-free coating agents (col. 10 lines 49-54).

57. One of ordinary skill in the art at the time the invention was made would have found it obvious to coat the chewing gum of Bunczek et al. with a coating as taught by Meyers in order to provide storage stability to the chewing gum since it is well known to coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective. Additionally, coating the chewing gum of Bunczek et al. would not have required undue experimentation as one of ordinary skill would have been familiar with the coating of chewing gum products as claimed.

### ***Double Patenting***

58. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-6, 8, 10-13 and 15-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 13-18, 24-26, 28-39 and 40-54 of copending Application No. 11/088,109.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim chewing gum comprising at least two different biodegradable polymers. The different glass transition temperatures and molecular weights of the instant claims are considered to be obvious over the conflicting claims where the at least two different biodegradable polymers perform the different functions of elastomer and elastomer plasticizer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

59. Applicant's arguments, see Remarks, filed May 5, 2009, with respect to the rejection of the claims under Goldberg and Grijpma have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bunczek et al. and Cook et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 7:30 AM to 5:00 PM (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./  
/Lien T Tran/  
Primary Examiner, Art Unit 1794

Nikki H. Dees  
Examiner  
Art Unit 179494